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No._____

In The
Supreme Court of the United States

DR. GEORGE PIECZENIK

Petitioner,

v.

DYAX CORPORATION

Respondent.

On Petition For Writ of Certiorari To The Appeals Court Of the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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Questions Presented for Review

1) Whether Dr. Pieczenik, *pro se*, was denied his Sixth Amendment right to effective assistance of counsel when the District Court denied a motion by both Plaintiff and Defendant to retain Plaintiff's counsel?

2) Whether Dr. Pieczenik, *pro se*, was denied his Fourteenth Amendment right to Due Process when the District Court did not take into account every element of evidence of infringement from New England Biolabs and a fraudulent affidavit by Dyax and Counsel?

3) Whether Dr. Pieczenik, *pro se*, was denied his Constitutional Right to enforce his patent under Article 1, Section 8 as the Court of Appeals for the Federal Circuit did not account for the judicial history, USPTO and public policy for "written description" in 35 USC 112 para 1 which requires both a functional and a structural description for nucleic and amino acid claim structures containing combinatorial library elements such as "all possible peptide sequences of a given length"?

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Authorities, Citations, and Patents Cited

CF. Teleflex, Inc. v. Ficosa N. Am. Corp. 299 F.3rd 1313, 1329 (Fed.Cir. 2002)

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*Hoffman La Roche, Inc. vs Promega Corp.*323 F.3rd 1354(Fed.Cir 2003)p.20

Lampi Corp. v. American Power Products Inc., 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) p.9

Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997). p.10

THE PIECZENIK PATENTS

U.S.Patents 6,605,448; 5, 866, 363; 4, 359, 535 and 4, 528, 266

PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES SUPREME COURT

I, Dr. George Pieczenik, *pro se*, respectfully request that the Honorable Justices of the Supreme Court grant a Writ of Certiorari to review the judgment of the Court of Appeals for the Federal Circuit rendered on September 23, 2003.

OPINIONS BELOW

The opinion of the Court of Appeal for the Federal Circuit is the subject of this Petition is Pieczenik v Dyax 226F.Supp.2d 314(D.Mass.2002) and is set forth as Appendix

STATEMENT OF THE BASIS FOR JURISDICTION

I, Dr. George Pieczenik, *pro se*, believe I may petition the Court under Title 28 of the United States Code § 1254 and §1257(a) 2002 to review the ruling of the Court of Appeals for the Federal Circuit as decided September 23, 2003.

Background: Ruling of Judge Rader- See Attached Appendix I

Court of Appeals for the Federal Circuit Errs in Claim Interpretation

Unfortunately, it seems that the Court of Appeals for the Federal Circuit has misread the claim construction of the three issues I defined and they addressed. It appears that they have not seen or read the Memorandum in Lieu of Oral Argument which is given again in Appendix II. This memorandum clearly narrowed the issues to the three elements in claim construction.

The three elements are the terms 1) "having" or "has" vs "comprising", 2) "combinatorial library" vs "all possible peptide sequences for a given length"' and 3) the term "oligonucleotide" in the 535, 266 patents vs the term "oligonucleotide" in the '363 patent.

The only term directly addressed in the Markman is the term "oligonucleotide". The term "combinatorial library" is a contemporary scientific term for a population of "all possible peptide sequences". The Court of Appeals for the Federal Circuit did not address the definition of calculating "all possible peptide sequences". The District Court did address this issue though incorrectly calculated "all possible peptide sequences". The Court of Appeals for the Federal Circuit

stated that because the actual term "combinatorial" was not *per se* used in the claim construction the Court of Appeals would not address the issue. The use of the term "combinatorial" in the Appeal Brief was to simplify the concept of "all possible peptide sequences" so that the issue of calculating its size or "all the possibilities" could be addressed. As unobvious as this was to the Court of Appeals it is obvious to one skilled in the art that the phrase "all possible peptide sequences" in the context of this case is the issue of the "diversity of a combinatorial library". The Court of Appeals for the Federal Circuit should have addressed this issue as this is the pioneering patent in this area and dates to a filing date of 1985. This patent protects American inventors in this powerful method of research, drug design and vaccine development. This patent is the biotech equivalent of the Leo Szilard patent on nuclear fission. It is the pioneering patent.

"Having" or "Has" as an Open Term

Judge Rader correctly points out that substituting "comprising" for "having" in claim 24 and 34 at the positions he assumes this substitution is required does read the specificity –"in particular, the upper bound of 'about 12' out of the claim. However, he has placed the substitutions in the wrong position.

This was clearly discussed in a re-hearing request

brief in the Circuit Court and in the Memorandum in Lieu of Oral Argument in the Court of Appeals for the Federal Circuit. This suggests this Memorandum was not read as Judge Rader is a specialist in claim construction.

As evidence for my statement, I repeat specific claims below and outline in bold letters where the semantic substitution should have been made by Judge Rader and where they have been made by the USPTO in the patent continuation US 6,605,448. In contrast to Judge Rader's statement that the semantic substitution reads out the upper bound of "about 12" out of the claim in his context, it does not read out the upper bound of "about 12" out of the claim in the proper semantic context shown below (in patent '448).

An example is given of where the conversion of "having" or "has" to "comprising" is appropriate and was the example in my Court of Appeals for the Federal Circuit brief and my Memorandum in Lieu of Oral Argument is the following:

Claim 22 of '448 is aligned with the earlier version Claim 24 of '363 at issue and claim 23 of '448 is aligned with the earlier version of Claim 34 of '363. In claim 24 of '363 the term "**has**" is replaced by the term "**comprising**" in the region of the claim "**said oligonucleotide population comprises a coding region**" rather than " has a coding

region" which is where Judge Rader has placed the replacement. In claim 34 of '363 the phrase "**has a length**" is replaced by the phrase "**comprises a length**". In the semantic context intended and misunderstood by the Court, this clearly is to be interpreted as "open". This semantic context means the claim is to be interpreted as an oligonucleotide sequence in a population of oligonucleotides which contains within and among other sequences a "combinatorial library" sequence or codings for "all possible peptide sequences of a given length".. This issue was clearly discussed in the Circuit Court in my Re-Hearing Brief as well as Appendix evidence from the USPTO supporting this view. This brief should have been sent with my file to the Court of Appeal to the Federal Circuit.

Patent '448

Claim 22. A population of recombinant vectors comprising substantially identical autonomously replicating nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein a member of an oligonucleotide population, wherein each member of said oligonucleotide population **comprises** a coding region comprising a length from about 4 to about 12 nucleotide triplets that encodes a corresponding peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein

the sum of corresponding peptide sequences encoded by said oligonucleotide population represents at least about 10% of all possible peptide sequences of said length, and wherein each member of said oligonucleotide population is contained in said recombinant vector population, and wherein the recombinant structural genes are expressed upon transfer of said recombinant vectors into Escherichia coli host cells, and wherein expression of said recombinant structural genes yields polypeptides, each polypeptide comprising said corresponding peptide sequence.

Patent '363

Claim 24. A population of recombinant vectors comprising: substantially identical autonomously replicating nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein a member of an oligonucleotide population, wherein each member of said oligonucleotide population **has** a coding region having a length from about 4 to about 12 nucleotide triplets that encodes a corresponding peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein the sum of corresponding peptide sequences encoded by said oligonucleotide population represents at least about 10% of all possible peptide sequences of said length, and wherein each member of said oligonucleotide population

is contained in said recombinant vector population; and wherein the recombinant structural genes are expressed upon transfer of said recombinant vectors into Escherichia coli host cells, and wherein expression of said recombinant structural genes yields polypeptides, each polypeptide comprising said corresponding peptide sequence

Patent'448

Claim 23. A method of producing a population of epitopic peptide sequences, comprising the steps of: Providing a population of recombinant E. coli cells, each of said cells containing at least one member of a recombinant vector population, each member of said vector population comprising substantially identical autonomously replicating nucleic acid sequences, said nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein a member of an oligonucleotide population wherein each member of said oligonucleotide population comprises a coding region **comprising a length** from about 4 to about 12 nucleotide triplets that encodes a corresponding peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein each member of said oligonucleotide population is contained in said recombinant vector population and wherein the sum of said corresponding epitopic peptide sequences represents at least about 10% of

all possible peptide sequences of said length: and culturing said recombinant E. coli cells to allow expression of said recombinant structural genes such that said epitopic peptide sequences are accessible to antibody recognition.

Patent '363

Claim 34. A method of producing a population of epitopic peptide sequences, comprising the steps of: providing a population of recombinant E. coli cells, each of said cells containing at least one member of a recombinant vector population, each member of said vector population comprising substantially identical autonomously replicating nucleic acid sequences, said nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population **has a length** from about 4 to about 12 nucleotide triplets that encodes a corresponding epitopic peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein each member of said oligonucleotide population is contained in said recombinant vector population and wherein the sum of said corresponding epitopic peptide sequences represents at least about 10% of all possible peptide sequences of said length; and culturing said recombinant E. coli cells to allow expression

of said recombinant structural genes such that said epitopic peptide sequences are accessible to antibody recognition

This change of interpretation of "having" or "has" in this semantic context is very much in line with an "open" interpretation. The court examined the term "having" rather than the term "has". Both terms occur within the claims and in this sense may have led to a misunderstanding and misinterpretation of the "openess" of the combinatorial library context.

Phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited). However, Judge Rader only mentioned without citation *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) and stated that the term "having" for instance, does not create a presumption that the body of the claim is open".

However, in the context of biotech inventions the more appropriate case is the *Regents of the Univ. of Cal. v. Eli Lilly & Co., 119* F.3d 1559, 1573, 43 USPQ2d 1398, 1410

(Fed. Cir. 1997). In this case the context is a cDNA having a sequence coding for human PI, and the term "having" still permits the inclusion of other moieties. This is identical to the interpretation of "**has**" and "**has a length**" of (nucleotide sequence or oligonucleotide) and more to the point than the *Crystal v. TriTech_* citation. However, given the improper semantic context which Judge Rader placed "having", then, all citations are irrelevant. What is needed is another Markman ruling addressing this issue in another but similar infringement case.

Combinatorial Library vs '"Oligonucleotide Population" coding for "all possible peptide sequences of a given length"'

Judge Rader correctly points out that the term "combinatorial library" was not used. Was he correct then in ignoring this issue? Perhaps. It certainly saves the Court from addressing a very difficult issue, which should now be addressed by the Supreme Court.

However, had the Court of Appeals for the Federal Circuit addressed this issue, it would have given guidance to the USPTO in a newly evolving area of patent law. This issue will be addressed at some future date in perhaps another similar patent case. The issue of a functional aspects of a structural definition of " all possible peptide sequences" or

"combinatorial libraries" i.e. to bind, was avoided by the Court of Appeals for the Federal Circuit.

However, both the Circuit Court and the Court of Appeals for the Federal Circuit spent an enormous amount of time addressing the issue of the structural definition of "oligonucleotide". Both ignored, however, the functional aspect of the definition of "oligonucleotide" in that scientifically the definition depends on whether it is chemically synthesized or isolated from nature. The synthesized "oligonucleotides" are generally smaller.

The Court of Appeals for the Federal Circuit rests its definition on medical dictionary references and ignores the scientific text evidence presented i.e. the Lehninger textbook reference. Did the Court see this filing? Clearly not. The Court actually had to *nunc pro tuncs* these definitions back in time to 1985 rather than accept the scientific text evidence of the time from Lehninger.

This is trivial compared to the lack of courage of the Court of Appeals for the Federal Circuit to define "combinatorial libraries" or " all possible peptide sequences of a given length". I as a *pro se* litigant have risked both my career and my patent to bring this issue to this Court for public policy reasons. I believe that the health and welfare of the American public to be quickly protected from viral and

bacteriological attack is at risk if this extremely rapid method of creating protective compounds is not protected in the United State's interest. At present, no majority owned United States company is using this methodology because of foreign patent injunction in U.S. courts. Dyax's largest share holder is a division of Deutche Bank.

In addition, Judge Rader makes an extremely large calculation error. This clearly suggests that his and the Courts understanding of the invention and the claims is completely wrong. The USPTO examiner Mindy Meischer also made an extremely large calculation error in calculating "combinatorial library" size. She inverted the base with the exponent. Fish and Neave used this calculation to convince Judge Stearn that their method of calculation, which has no basis in the scientific literature, but is sworn to in affidavits, is the proper method of calculating diversity size.

Judge Rader's mathematical reasoning starts off correctly and then it collapses. The passage he quotes is '363 column 3 II. 58-62 col 4,II, 41-51.ie "The number of tandem repeats can be from two to about 50 in number". Then the Judge states that "These passages indicate that an oligonucleotide has from two to about fifty tandem repeats, i.e., an oligonucleotide is a polymer with a number of nucleotides ranging from four to about one hundred."

This is just wrong. The invention is that each of the repeats is not an oligonucleotide but an oligonucleotide length that codes for a peptide that binds an antibody or a length claimed. The binding range is in the range of 4-7 amino acids or 12 to 21 nucleotides on average. A preferred embodiment is listed'363 col 4 II, 10-11. "It is particularly preferred that there be five amino acid residues in each oligopeptide" which is between 4-7 amino acids. Therefore, two to fifty tandem repeats would be anywhere from 24 nucleotides (two times 4 amino acids times 3 nucleotides per amino acid) to 1,050 nucleotides (50 times 7 amino acids times 3 nucleotides per amino acid). Therefore, the range of lengths of "oligonucleotides" in the section Judge Rader cites is not 2 to 100 nucleotides but 24 to 1,050 nucleotides if one takes into account the functional aspect of these coding oligonucleotides which is to be "accessible to antibody recognition" or binding by antibodies. This is part of the functional definition of "oligonucleotides" in that these "oligonucleotides" code for binding epitopes.

If we take Judge Stearns definition of these oligonucleotides and Judge Rader's definition of being from 3 to 13 amino acids in tandem repeats of 2 to about 50 than the numbers are much larger than Judge Rader's 2 to 100 nucleotides. They are in the range of 3amino acids times 3 nucleotides per

amino acid times 2 tandem repeats or 18 nucleotides at the bottom of the range. The top of the range is 13 times 3 nucleotides per amino acid times 50 tandem repeats or 1950 nucleotides. This is almost 200% larger number of nucleotides than Judge Rader calculates. It also means he and the Court did not understand the functional aspect of why even tandem sequences could also identify epitopic bindings of antibody recognition and, thereby, the crux of the invention. The beauty of this invention is that it is independent of size and depends on the diversity having a statistical chance of containing an antibody binding sequence, *inter alia.*

If Judge Rader and Judge Stearn had properly calculated the size of the "oligonucleotides" than the size is well within the acknowledged 18 nucleotide triplets of Dyax's lowest claimed library including scaffolding.

However, Judge Rader somehow is willing to overlook this allowed "lexicography" to state that any error on the part of the district court is "harmless" using two arguments. One is that Judge Rader claims that the "'535 and '266 patents do not share the same lineage as the '363 patent" in spite of the fact that the '535 and the '266 patents are incorporated by reference see '363 col 8 II, 63-65. Incorporation by reference requires that the terms in the

specification use the terms in a similar manner as in the incorporated references and is part of the need for "completeness" in an application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). To argue then that patents that are incorporated by reference do not share the same lineage is an oxymoron. Judge Rader then cites a trivial patent case involved with the best enablement disclosure of a "clip". Ironically, he interprets his own ruling in this case improperly in this instance. He quotes himself " If a reasonable juror could have found literal infringement under a more narrow reading of claim 1, then the same reasonable juror could not have avoided finding literal infringement under the correct, broader construction of the claim. Thus the district court's error was harmless."

However, in calculating "all possible peptide sequences of a given length" then the narrow interpretation of the claim is the "smaller" oligonucleotide definition. Thereby the size of the diversity is smaller and the infringement more likely. However, if the broader interpretation of the claim is the "larger" oligonucleotide definition, than the size of the diversity is larger and the infringement is less likely. This is just the opposite of what a "reasonable juror" would find. Judge Rader's "reasonable juror" would also have a 10 pound ball falling twice as fast as

a 5 pound ball. Newton's interpretation of gravity requires that they fall at the same speed. Science, mathematics and gravity do not work in the manner of Judge Rader's "reasonable juror" nor do calculations of "all possible peptide sequences of a given length".

In summary, Judge Rader avoided the more interesting and difficult issues of defining a combinatorial library in terms of structure and identify specific antibody epitopes) which is necessary for public policy, USPTO policy and vaccine development. Then he misread the actual patent in terms of inserting "open" terms in claims in improper semantic locations and then miscalculated the size of tandem repeats by a magnitude.

The issue of the embeddedness of combinatorial libraries or calculating "all possible peptide sequences" of any given length and the inherent nested nature of these sequences have been completely avoided. It seems that Judge Rader was not given the Memorandum in Lieu of Oral Argument as he did not address any of the clear explanations and arguments given in this memorandum. He ignored Judge Stearns' interpretation of combinatorials as being proportional to the size of the jar containing the combinations possible for different colored balls in the jar rather than the number of different balls themselves. This is contrary to

logic and math.

One other point is that Judge Rader overlooked is the file from the District Court where the issue of his statement that "Dr. Pieczenik did not oppose Dyax's cross-motion for summary judgment of non-infringement of those patents" was addressed . It is clear from the Re-hearing motions in the District Court that the cross-motion was never served on Dr. Pieczenik for him to oppose. The *pro se* status of a litigant is historically based in the disgust of the American revolutionist to the British habit of appointing lawyers to represent the colonists without defending their interest or lives. The revolutionist feelings on *pro se* representation was similar to Judge Newman's other ruling in *Hoffman La Roche, Inc. vs Promega Corp.* 323 F.3rd 1354 (Fed.Cir 2003) case where she stated very clearly that the time has arrived where " all patent attorney's are jackals" . Charles I made extensive use of the Court of Star Chamber and appointed counsel to persecute dissenters, including the Puritans who fled to New England. This places the issue of *pro se* representation at the very roots of the American judicial system. Clearly this origin has been forgotten and the *pro se* litigant is now sorely much abused by the judicial system.

The District Court has discriminated against this *pro*

se litigant in not re-opening the case when the District Court was informed that the litigant was not served while in *pro se* status. In addition, the District Court denied the *pro se* litigant his request for time to obtain counsel. The Court of Appeal for the Federal Circuit disregarded these *pro se* discrimination issues either because they did not receive the files from the District Court containing these motions or they were not at issue in this Appeal except for Judge's ruling of non-infringement was based on supposedly unopposed motions and affidavits. The District Court's willingness to allow Fish&Neave to win in this case on "sewer service" of a *pro se* litigant is the level of judicial conduct routinely used in New York City housing pseudo-court and, also, approved by those .pseudo-judges. In addition, the District Court ignored *pro se* Plaintiff's evidence of a fraudulent affidavit introduced by Dyax and Fish&Neave concerning the New England Biolabs combinatorial libraries. Appendix IV which proves *res ipsa loquitur* that Dyax infringed the Pieczenik patents even under the constraints of the CAFC's and the District Court's Markman ruling.

CONCLUSION AND PRAYER

I move, in this petition, that the Supreme Court of the United States properly address the issue of claim construction in populations of DNA sequences coding for "all possible peptides for a given length" a.k.a combinatorial libraries and in so doing reverse the rulings of the Court of Appeal for the Federal Circuit and the District Court and find for Dyax infringing the Pieczenik patents.

I further declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct. Signed this day of 26 th of November, 2003 at New York City, New York.

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APPENDIX I

NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record. This disposition will appear in tables published periodically.

United States Court of Appeals for the Federal Circuit

03-1302

GEORGE PIECZENIK,

Plaintiff-Appellant,

V.

DYAX CORP.,

Defendant-Appellee.

DECIDED: September 23, 2003

Before NEWMAN, MICHEL, and RADER, Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the District of Massachusetts determined that Dyax Corp. did not infringe U.S. Patent Nos.4,359,535 (the '535 patent), 4,528,2661 (the '266 patent), and 5,866,363 (the '363 patent). Pieczenik v. Dyax Corp., 226 F. Supp.2d 314 (D.Mass.2002); Pieczenik v. Dyax Corp., Civ. Action No. 00-11370-RGS (D. Mass. Feb. 25,2003). This court affirms.

[1] The '266 patent is a divisional of the '535 patent.

I.

In its Markman ruling, the district court construed two phrases appearing only in the '363 patent: "from about 4 to about 12" and "at least about 10% of all possible peptide sequences" Pieczenik, 226 F. Supp.2d at 321. In addition to the two phrases in the claims of the '363 patent, the district court construed one claim term, "oligonucleotide," in the claims of the '363, '535, and '266 patents. Pieczenik, 226 F. Supp.2d at 322. After the district court construed the claims, Dr. Pieczenik moved for partial summary judgment of infringement of the '363 patent. Dyax, in turn, cross-moved for summary judgment of noninfringement of all three asserted patents. Apparently conceding noninfringement of the '535 and '266 patents in light of the district court's claim construction, Dr. Pieczenik did not oppose Dyax's cross-motions for summary judgment of noninfringement of those patents. Accordingly, the district court granted Dyax's motion on the '535 and '266 patents.

Dr. Pieczenik, however, did not concede noninfringement of the '363 patent. Nevertheless, Dr. Pieczenik did not dispute the facts introduced by Dyax, and thus the district court deemed those facts admitted. It, therefore, granted summary judgment on the asserted claims of the '363 patent,

explaining:

Because it is undisputed that (1) Dyax's phage libraries do not meet the "about 4 to about 12" claim limitation (according to the affidavit of Robert Ladner, Dyax's Chief Scientific Officer, the smallest Dyax library is 18 nucleotide triplets in length, while the largest exceeds 100 nucleotide triplets), and (2) that Dyax's phage libraries do not meet the "at least about 10% of all possible peptide sequences" claim limitation (according to the Ladner affidavit the actual number for all libraries is less than one trillionth of the possible peptide sequences), there can be no literal infringement

Pieczenik, Civ. Action No. 00-11 370-RGS, slip op. at 4 (D. Mass. Feb. 25, 2003). The district court also determined that Dyax's accused products would not infringe the '363 patent under the doctrine of equivalents.

II.

A determination of infringement requires two steps. "First, the court determines the scope and meaning of the patent claims asserted. [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted). Step one, claim

construction, is an issue of law, Markman v. Westview Instruments. Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), affd, 517 U.S. 370 (1996), that this court reviews without deference, Cybor, 138 F.3d at 1456. Step two, comparison of the claim to the accused device, is a question of fact that requires the patent holder to establish that the accused device includes every claim limitation or its equivalent. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). Summary judgment is appropriate where the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby. Inc., 477 U.S. 242, 247 (1986). This court reviews a grant of summary judgment by a district court de novo. Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1355-56 (Fed. Cir. 2000).

Dr. Pieczenik's appeal focuses solely on the district court's claim construction. This court understands that Dr. Pieczenik argues for the construction of three terms, only one of which coincides with the terms that the district court addressed. Specifically, Dr. Pieczenik appeals the constructions of "combinatorial libraries," "having," and "oligonucleotide."

"In construing claims, the analytical focus must begin

and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which patentee regards as his invention." Interactive Gift Express, Inc. v. Compuserve. Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quotation omitted). The terms used in the claims bear a "heavy presumption" that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art. CCS Fitness. Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). With respect to the ordinary meaning of the words, a court may consult a dictionary, encyclopedia, or treatise. Tex. Digital Sys.. Inc. v. Telegenix Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). Moreover, "[a]bsent an express intent to impart a novel meaning, claim terms on take their ordinary meaning." Elektra Instrument S.A. v. O.U.R. Scientific Int'l. Inc., 214 F.3d 1302,1307 (Fed. Cir. 2000).

As previously noted, Dr. Pieczenik's appeal invokes two terms that were not addressed by the district court: "combinatorial libraries" and "having." As an initial matter, this court notes that "combinatorial libraries" does not appear in any of the claims of the asserted patents. Because claim construction requires focus on particular claim language, this court is reticent to construe a term not present in the claims,

especially a term not construed by the district court. Accordingly, Dr. Pieczenik's challenge with respect to "combinatorial libraries" fails. Vivid Techs., Inc. v. Am. Sci. & Eng'g. Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

Dr. Pieczenik argues that "having" is open-ended and, thus, equivalent to "comprising." While "having" may mean, in certain contexts, "comprising," this court has never equated the two:

The transition "having" can also make a claim open. However, the term "having" does not convey the open-ended meaning as strongly as "comprising." "Having ," for instance, does not create a presumption that the body of the claim is open.

Crystal Semiconductor Corp. v. TnTech Microelectronics Int'l. Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001) (citation omitted). Examining the term within context of the claims, this court concludes that this usage of "having" is closed.

The asserted independent claims of the '363 patent, namely claim 24 and 34, contain the phrases "said oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets" and

"each structural gene having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets." '363 patent, col. 46, II. 55-57; col. 47, II.. 56-60. Because the claims refer to a coding region that designates multiple nucleotide triplets, i.e., about 4 to about 12, the claims manifest an objective intent to close their scope to oligonucleotide populations consisting of members of specified lengths. In other words, substituting "comprising" for "having" would read the specificity—in particular, the upper bound of "about 12"—out of the claim. See Tex. Instruments. Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993). Thus, "having," in this context, is closed.

Lastly, Dr. Pieczenik challenges the construction of "oligonucleotide." Rather than construe the claim blindly, this court begins with a careful consideration of the district court's opinion regarding this claim term. Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 713 (Fed. Cir. 1998). With respect to the '535 and '266 patents, Dr. Pieczenik argued before the district court that "'oligonucleotide' as used in these two patents would be understood by a person of ordinary skill in the art to mean a polymer of nucleotides

comprising at least a few nucleotides in
length and not usually more than about 100.'" Pieczenik, 226 F.Supp.2d at 322 (quoting Dr. Pieczenik's Markman Brief at 18). With respect to the '363 patent, however, Dr. Pieczenik argued that the file history "'makes clear' that the 'oligonucleotide' as used in that patent signifies an oligonucleotide with 'an upper limit at about 600 to about 750 nucleotide triplets in length.'" Id. (quoting Dr. Pieczenik's Markman Brief at 8). But the district court dismissed Dr. Pieczenik's attempt to broaden the plain meaning of oligonucleotide using the '363 patent's prosecution history, instead construing the term according to scientific and medical texts. The district court thus construed oligonucleotide as "a compound created by the condensation of a small number of nucleotides with 20 specified as the upper limit." Id.

Because the '535 and '266 patents[2] do not share the same lineage as the '363 patent, their claim terms in the first two patents must be construed separately. See Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301 (Fed. Cir. 2001). Independently evaluating the specifications of the '535 and '266 patents, this court agrees that there is no "express intent to impart a novel meaning." Elektra Instrument, 214 F.3d at 1307. Thus, "oligonucleotide" takes its common, ordinary

meaning with respect to these patents. Dyax provides three references that define "oligonucleotide."[3] The first defines it as "[a] compound made up of a small number of nucleotides (2 to 10)." Melloni's Illustrated Medical Dictionary 343 (1979). The second defines it as "a polymer made up of a few (2 to 10) nucleotides." Dorland's Illustrated Medical Dictionary 920 (26th ed. 1981). And the third defines it as "[a] compound made up of the condensation of a small number of nucleotides." Stedman's Medical Dictionary 980 (24th ed. 1982).[4] Because these definitions do not vary significantly, this court holds that "oligonucleotide" means, for the purposes of the '535 and '266 patents, "a compound made up of two to ten nucleotides." Even though this

[2] Neither party has argued that because the '266 patent is a divisional of the '535 patent, they should be analyzed separately. Thus, the court assumes that the same interpretation should be treated as the same. See Desper Prods.. Inc. v. QSound Labs. Inc., 157 F.3d 1325, 1338 n.5 (Fed. Cir. 1998).

[3] The ordinary, common meaning of "oligonucleotide" is not alleged to have changed between the filing date of the '535 patent, i.e., Oct. 1, 1979, and the issue dates of the '535 patent, i.e., Nov. 16, 1982, or the '266 patent, i.e., Jul. 9, 1985. Thus, this court need not decide which precise date

among those should fix the meaning. Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1370 n.1 (2002).

[4] A later version, published after the relevant timeframe, refines the definition: "A compound made up of the condensation of a small number (typically less than twenty) of nucleotides." Stedman's Medical Dictionary 1244 (26th ed. 1995

court adopts a slightly different claim construction than the district court, any error is harmless. A determination of noninfringement under a broader claim construction compels a determination of noninfringement under a narrower claim construction. Cf. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1329 (Fed. Cir. 2002) ("If a reasonable juror could have found literal infringement under a more narrow reading of claim 1, then the same reasonable juror could not have avoided finding literal infringement under the correct, broader construction of the claim. Thus, the district court's error was harmless.").

The '363 patent, however, yields a different conclusion. The patentee became a lexicographer and particularly defined "oligonucleotide." See Beachcombers Int'l. Inc. v. Wildewood Creative Prods.. Inc., 31 F.3d *1154,* 1158 (Fed. Cir. 1994). In part, the patent states:

The oligonucleotide population may also be composed of members, each of which contains the same number of tandem repeats of each peptide coding sequence, where the number of tandem repeats is from two to about fifty.

*****

The recombinant vector population can also be made up of individual vectors each containing the same number of tandem repeats of an oligonucleotide sequence as defined

above. The number of tandem repeats can be from two to about fifty in number.

The recombinant vector population can also be made up of individual vectors each containing the same number [of] tandem repeats of an oligonucleotide sequence as defined above. The number of tandem repeats can be from two to about fifty in number.

'363 patent, col. 3, II. 58-62; col. 4, II. 41-51. These passages indicate that an oligonucleotide has from two to about fifty tandem repeats, i.e., an oligonucleotide is a polymer with a number of nucleotides ranging from four to about one hundred. Nevertheless, the context of the disputed claims of the '363 patent demonstrate that any error on the part of the district court was harmless.

As noted above with respect to "having," claims 24 and 34 recite similar limitations: "said oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets" and "each structural gene having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets." '363 patent, col. 46, II. 55-57; col. 47, II. 56-60. While "oligonucleotide" has a more expansive meaning set forth in the written description, these claims particularly limit

the number of nucleotide triplets to a number ranging from about 4 to about 12. In other words, the claimed oligonucleotides are chosen from an oligonucleotide population with lengths ranging from about 4 to about 12. The claimed oligonucleotides, therefore, are a subset of oligonucleotides as defined by the '363 patent. It is undisputed that the smallest Dyax library is 18 nucleotide triplets in length. Pieczenik, Civ. Action No. 00-11370-RGS, slip op. at 4. Accordingly, Dyax does not infringe claims 24 and 34 of the '363 patent.

This court considered Dr. Pieczenik's other arguments but finds none persuasive. Because the district court properly granted summary judgment of noninfringement of the '363, '535, and '266 patents, this court affirms.

Appendix II- Memorandum in Lieu of Oral Argument

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

03-1302

GEORGE PIECZENIK

PLAINTIFF-APPELLANT

V.

DYAX CORP.

DEFENDANT- APPELLEE

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Appeal from the United States District Court for the District of Massachusetts

In case no. 00-CV-11370, Judge Richard G. Stearns

==========

MEMORANDUM IN LIEU OF ORAL ARGUMENT

Prof. George Pieczenik, *Pro Se*

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Tel: 212-829-8491

Date: August 4, 2003

Issues before the Court:

a) The definition of a combinatorial library as described in Claims 24 and 34 in Pieczenik Patent 5,866,363.

1) District Court Errs in its Structural Interpretation of Combinatorial Library Size

The Pieczenik '363 patent is the pioneering patent in combinatorial chemistry. As such, it defined combinatorial libraries and methods of producing such combinatorial libraries recombinantly as well as chemically. The advantage of combinatorial peptide libraries is that all possible peptide sequences are synthesized *a priori* and then those sequences of interest are selected *a posteriori.*

Defining combinatorial libraries as a patent claim is what is at issue and revolves around a Markman interpretation by the District Court.

The District Court defined a combinatorial library in terms of the "insertion" length rather than the more conventional "library" length. That is, the sequence that is used to carry the library may be any size and is usually a unique non-combinatorial sequence. It is often time referred to as "scaffolding". This length definition is only important in that the lower Court improperly used this definition to calculate the size of a combinatorial library.

Unfortunately, opposing counsel and affidavits from Dyax's

scientist supported this view. This definition, however, is contrary to the proper scientific method of determining the size of a combinatorial library by using the actual "library" length independent of the "scaffolding". Therefore, a 5 amino acid combinatorial library has 20 to the 5th power of possible peptide sequences. A scaffolding of 10 constant amino acids on either side of this library would be erroneously calculated as being a library size of 20 to the 15th power by the District Court. Dyax's and F&N's use of "insertion" length for the legal community and "library" length for the scientific community is reminiscent of Nobel laureate Arafat's earlier use of Arabic for statements of terrorist support and English for statements condemning terrorists. Hopefully, in both cases, the statements will converge reasonably.

2) District Court Ignores the Intrinsic Matryoshka Aspect of Combinatorial Libraries

The other issue of defining a combinatorial library is the scientific fact that each combinatorial library has embedded combinatorial libraries. This is an intrinsic aspect of these chemical libraries and as such has many legal precedents associated with the patenting of intrinsic aspects as previously discussed in the original brief.

This issue is most clearly shown in Figure 1, shown

below. One sees that each of these dolls, representing a certain size combinatorial library, is nested inside a larger doll. A doll that represent the 20 to the 4^{th} combinatorial library is nested in a doll that represents 20 to the 5^{th} combinatorial library, which is in turn nested in a doll that represents 20 to the 6^{th}, etc.

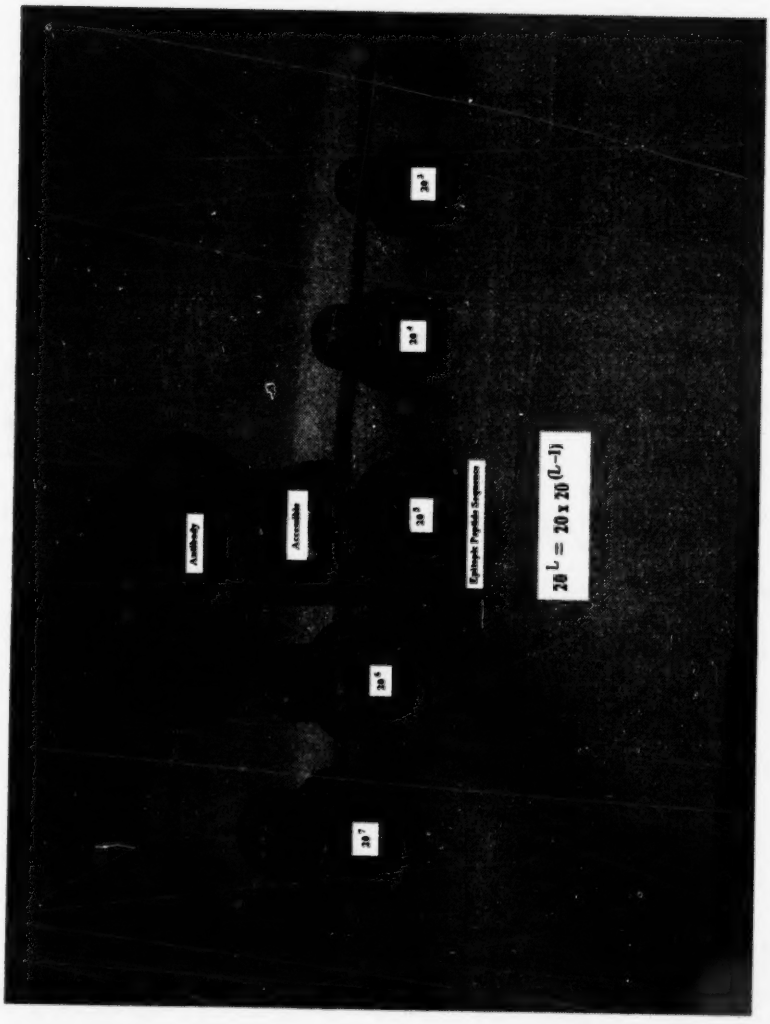
This argument can be summarized by the mathematical fact that 20 to the power L, where L represents the length of the "combinatorial library" and not the "inserted length" which equal 20 times the next smaller nested "combinatorial library" where that
next smaller nested library is represented by L-1. This combinatorial fact is obvious to any one of ordinary skill in the art as well as being a "mathematical truth" such as 2+2=4. Therefore, this could be a 7^{th} amendment issue to be tried by a jury rather than ruled on by the District Judge in a Markman hearing.

This nested aspect of a combinatorial library is re-enforced in the claims that are dependent on Claim 34 i.e. 35 and 36-46 which list all the nested libraries in the Claim 34 element "encodes a corresponding epitopic peptide sequence of from about 4 to about 12 L-amino acid residues".

3) District Court Errs in its Non-Functional Interpretation and its Erroneous Structural Interpretation by

Ignoring the "accessible to antibody recognition" Element of Claim 34 or *Corpora non agunt nisi fixite*

Another aspect of the functional aspect of the "nested" characteristic of combinatorial libraries is seen in Figure 1 where the "antibody" represented by the Inventor's two fingers select the Matryoshka doll representing the 20 to the 5^{th} combinatorial library. Antibodies will bind within a larger combinatorial library a smaller nested combinatorial library that is intrinsic to the larger library. It is of no use to have an antibody bind a combinatorial library that is larger than the largest combinatorial library. Therefore, it is intrinsic to these libraries that the binding size is smaller than the library size. This element is the "functional" element of this structural claim and cannot be disregarded in interpreting this claim. This is now a USPTO policy (see Dr. Pieczenik's Appendix to Reply Brief) for all patents which claim some unique nucleotide sequence structure.



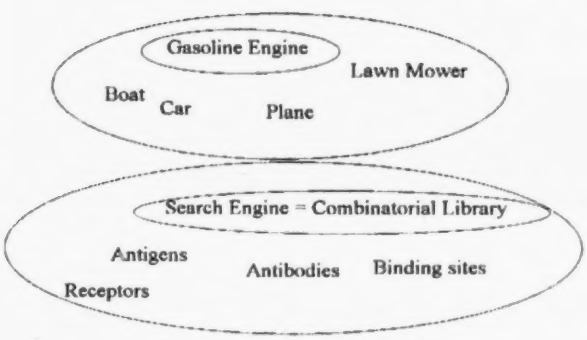
b) "Having" as an Open Term Equivalent to "Comprising"

The Venn Diagrams shown in Figure 2 is a visual representation of the open nature of the term "having" in Claim 34. It shows that a combinatorial library is functionally equivalent to a biochemical search engine. This

biochemical search engine can be used to define antigen, antibody, receptor and binding site specificities. It is a biochemical information engine that can be used in any context much like a gasoline

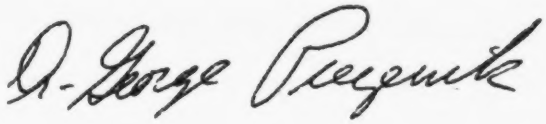
engine has been historically used to move any type of vehicle i.e. car, boat, plane, lawn mowers, *inter alia*.

Infringement therefore occurs when Dyax uses the biochemical search engine described in Claim 24 and 34 of Pieczenik patent 363 in any vector independent of actual "oligonucleotide" insertion size and only dependent on use of any of the combinatorial libraries described and the binding thereof and the binding thereof of their nested libraries.



VENN DIAGRAM

Respectfully submitted,



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Appendix III

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
CIVIL ACTION NUMBER 00-11370-RGS

GEORGE PIECZENIK AND
I.C. TECHNOLOGIES AMERICA, INC.
v.
DYAX CORP.
MEMORANDUM AND ORDER

September 18, 2002

STEARNS, D.J.

This decision follows a hearing held under the directives of Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). "Markman requires a trial judge in a patent case to construe and define the contested claims of a patent. The task committed to the judge is to explain what the protected invention is, and sometimes what it is not, ideally in language that will be accessible to a lay jury." Blown, Inc. v. Amgen, Inc., 18 F. Supp.2d 105, 106 (D. Mass. 1998).

As described by the inventor, Dr. George Pieczenik:

[t]he invention provides an efficient and convenient means for the identification and production of monoclonal antibodies to any specific region of any antigen or hapten of interest. Monoclonal antibody production, according to the invention, does not require antigenic stimulation of a host animal. This is a critical concept of the present invention. Such antigenic stimulation can be employed to increase the frequency for cognate hybridoma formation, but there will be a member of an antibody population (of a sufficiently large number of members) which will recognize the particular epitope even in the absence of such stimulation. The invention involves the antibody binding properties of a test species, e.g., a peptide, but is totally independent of the ability of the test species to induce an antigenic response in vivo. The invention permits the identification of the specific peptide sequence on a protein that is recognized by an antibody; i.e., the epitope. The specificity of antibodies recognizing distinct sequences, or epitopes, on the same antigen can be differentiated. In addition, the invention permits the characterization and the localization on a chromosome of the nucleotide sequence encoding the amino acid sequence recognized by an antibody. `363 Patent, Col. 5, Ins. 29-50.

The utility of the invention, according to plaintiffs, derives from its "library" of peptide sequences, which allows an "antibody binding specificity to be determined without previous knowledge of antigenic sequences," and its recognition "that the size of the

bindable universe (epitopic) and binding universe (antibody) is limited and thus can be enumerated, recognized and synthesized." Plaintiffs' Response, at 1.[1] The invention has practical application in the development of pharmaceutical products like vaccines. The principal patent in dispute, U.S. Patent No. 5,866,363 (the '363 patent), "Method and Means for Sorting and Identifying Biological Information," contains two partially disputed independent claims, numbered 24 and 34.[2]

The Disputed Claims

Claim 24 describes a "population of recombinant vectors" containing oligonucleotides that encode a population of peptides. It reads as follows:

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[1]There were two rounds of briefing, which are designated in this Memorandum as Plaintiffs' Brief, Dyax Brief, Plaintiffs' Response, and Dyax Reply.

[2]The '363 patent is a continuation-in-part of two earlier applications, the earliest of which was filed on August 28, 1985. Both of the earlier applications were ultimately

Claim 24. A population of recombinant vectors comprising: substantially identical autonomously replicating nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein a member of an oligonucleotide population, wherein each member of said

oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets that encodes a corresponding peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein the sum of corresponding peptide sequences encoded by said oligonucleotide population represents at least about 10% of **all possible peptide sequences** of said length, and wherein each member of said oligonucleotide population is contained in said recombinant vector population; and wherein the recombinant structural genes are expressed upon transfer of said recombinant vectors into *Escherichia coil* host cells, and wherein expression of said recombinant structural genes yields polypeptides, each polypeptide comprising said corresponding peptide sequence.
Claim 34 describes a method of producing the population of peptides described in claim 24. It reads as follows:

34. A method of producing a population of epitopic peptide sequences, comprising of the steps of:
providing a population of recombinant E. *coli* cells, each of said cells containing at least one member of a recombinant vector population, each member of said vector population comprising substantially identical autonomously replicating nucleic acid sequences, said nucleic acid sequences comprising a recombinant structural gene, each structural gene having inserted therein one member of an oligonucleotide population wherein each member of

said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets that encodes a corresponding epitopic peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein each member of said oligonucleotide population is contained in said recombinant vector population and wherein the sum of said corresponding epitopic peptide sequences represents at least about 10% of all possible peptide sequences of said length; and

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abandoned.

culturering said recombinant E. coil cells to allow expression of said recombinant structural genes such that said epitopic peptide sequences are accessible to antibody recognition.

The Markman dispute focuses on the proper construction of the following language in claim 24:

wherein each member of said oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets that encodes a corresponding peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein the sum of corresponding peptide sequences encoded by said oligonucleotide population represents at least about 10% of all possible peptide sequences of said length[.]

The parties also dispute the meaning of nearly identical language in claim 34:

wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets that encodes a corresponding epitopic peptide sequence of from about 4 to about 12 L-amino acid residues, and wherein each member of said oligonucleotide population is contained in said recombinant vector population and wherein the sum of said corresponding epitopic peptide sequences represents at least about 10% of all possible peptide sequences of said length[.]

Finally, the parties disagree over the proper definition of the term "oligonucleotide," as it is used in the claims of the `363 patent (and in two prior related patents). Legal Principles

"[C]onstruction of a patent claim is a matter of law exclusively for the court." Markman v. Westview Instruments, Inc., 52 F.3d 967, 977 (Fed. Cir. 1995) (citations omitted). "[A]n inventor is not [ordinarily] competent to construe patent claims" because "it is not unusual for there to be a significant difference between what the inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO." Solomon v. Kimblerv-Clark Corp., 216 F.3d 1372, 1380 (Fed. Cir. 2000). Thus, in construing the

claims of the patent, the court must adopt the perspective of a hypothetical practitioner of ordinary skill in the patent art as of the date of the original application. Weiner v. NEC Electronics, Inc., 102 F.3d 534, 539 (Fed. Cir. 1996), overruled on other grounds by Cvbor Corp. v. FAS Technologies, Inc., 138 F.3d 1448 (Fed. Cir. 1998).

The hierarchy of accepted analytical tools requires a court to begin its analysis with the intrinsic evidence of record. A court should first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996), citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). The court should next look to the patent specification. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make it and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. Finally, the prosecution history of the patent may be consulted. "[T]he record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims," Vitronics, 90 F.3d at 1582, but "it too cannot 'enlarge, diminish, or vary' the limitations in the claims."

Markman, 52 F.3d at 980.

The claims, specifications and file history constitute the patent's "public record .. on which the public is entitled to rely." Vitronics, 90 F.3d at 1583. Thus, it is inappropriate for a court to consider extrinsic evidence, such as expert testimony, unless the testimony is necessary to understand the meaning or scope of a technical term in the claims. Id., citing Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995); Markman, 52 F.3d at 980-981 (same). Expert testimony "may not be used to vary or contradict the claim language. . . . Nor may it contradict the import of other parts of the specification. Vitronics, 90 F.3d at 1584 (citation omitted). "[W]here the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Id., at 1583.

Discussion

The Competing Constructions

(a) "from about 4 to about 12 [nucleotide tripletsl EL-amino acid residuesl"

Plaintiffs construe this limitation, which is common to both claims, as encompassing lengths of from 3 to 13 *random* triplets.[3] Plaintiffs' argument focuses on the word "about" and its "clear warning" that exactitude is not being claimed. Plaintiffs' Response,

at 5. Dyax's counter-construction centers on the consistent use by the patentee of the definite integers 4 and 12. "Nowhere in the specification did the patentee say that any integer within the range should be afforded anything other than its ordinary accustomed meaning.

Indeed, in the specification, when the patentee wished to refer to an amino acid sequence of length 12, he used the number 12; when he wished to refer to a length of 7 amino acids he used the number 7; and when he wished to refer to a 5 amino acid sequence, he used

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[3]Dyax disputes any requirement that the triplets be random. The limitation that the oligonucleotide sequences (or the corresponding peptide sequences) be "random" appears nowhere in the language of the disputed claims, although it does appear in a number of other claims of the patent. As plaintiffs acknowledge, **courts** should normally not introduce into a claim by interpretation "limitations that are explicitly contained in other claims." Caterpillar Tractor Co. v. Berco, S.p.A., 714 F.2d 1110, 1116 (Fed. Cir. 1983).

the number 5." Dyax Brief, at 19. Thus, according to Dyax, "from about 4 to about 12" means from 4 to 12.[4]

(b) "and wherein the sum of fcorresponding peptide sequences) [claim 241 [said corresponding epitopic peptide sequences) (claim 34) [encoded by said oligonucleotide population) [claim 24] represents at least about 10% of all possible peptide sequences of said length"

While written slightly differently in the two claims, this limitation refers to the size of the peptide library needed to make the invention work. Plaintiffs offer no consistent construction of what is meant by "about 10% of all possible peptide sequences," but suggest that "10%" can consist of: (1) 300,000 (or perhaps 30,000) distinct members for any coded library of random peptides with a length in the range of 5 to 13 amino acid residues; (2) 16,000 (or perhaps 1,600) distinct members for any coded library of random peptides with a length of 4 amino acid residues; and (3) 80 (or perhaps 800) distinct members for any coded library of random peptides with a length of 3 amino acid residues. [5]

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[4]Dyax does not address the significance of the term "about" because of what I believe is a mistaken premise that the meaning of words of qualification has no relevance to a "literal" Markman construction, but "is more properly an issue relating to the availability

or nonavailabilityof.the_doctrine of equivalents." Dyax Brief, at 25-26 n.**. On this point, plaintiffs are correct that "[a]ll the limitations of a claim must be considered meaningful," Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991), a principle of claims construction that Dyax elsewhere acknowledges in its brief.

[5]The suggested population figure of 80 tripeptides may be a mathematical er[r]or. It is possible that plaintiffs meant 800 rather than 80 as $20^3/10 = 800$. Plaintiffs' calculations for populations of tetrapeptides and pentapeptides are largely faithful to the formula $0.10 \times L = 20/10$), reporting the accurate result of $20^4/10 = 16{,}000$ for tetrapeptides, and the approximately accurate result of $20^5/10 = 300{,}000$ for pentapeptides. Nonetheless, the parentheticals following the two calculations (suggesting the figures of 1,600 and 30,000 respectively) are consistent with the assertion that 10% in fact means 1%.

Plaintiffs' Brief, at 11, 16. The limitation "all possible peptide sequences of said length" plaintiffs construe to mean "the complete range of possible epitopic peptide sequences .. . within the range of

3 to 13 L-amino acid residues consistent with the means by which the 'oligonucleotide population' was generated." Id., at 11.

According to Dyax, the 10% limitation requires that the total of the peptide sequences encoded by the oligonucleotide population encompass at least 10% of the possible peptide sequences of a single given length within the range of from 4 to 12 L-amino acids. "All possible peptide sequences of said length," Dyax construes to mean the number of sequences derived by the formula $L = 20^{L}$ where ^{L} represents the given length within the specified range of L-amino acid residues and 20 signifies the number of genetically encodeable amino acids. Thus, if L is 12, the possible number of sequences is 20^{12} or 4.096×10^{5}, which when divided by 10 yields a library of 4.096×10^{14} members. Dyax Brief, at 13-14.

Analysis

The parties' dispute boils down to a basic difference in interpretation that plaintiffs accurately summarize as follows: "Dyax argues that [infringement] should be determined from the perspective of the size of the peptide library made, whereas plaintiffs' position is that infringement is determined by the size of the peptide library necessary to bind the desired target." Plaintiffs' Response, at 2. Plaintiffs, in other words, maintain that as Dr. Pieczenik refined his invention, he came to the realization that "five amino acids [the pentapeptide] is *a representative length* of peptide sequences

which can bind with differential specificity to an antibody." Plaintiffs' Brief, at 14 (emphasis in original).

Moreover, "antibodies are *now known* to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids." Plaintiffs' Response, at 10 (emphasis added). Thus, "the entire universe of antibodies is equivalent to the entire universe of epitopic peptides that are 5 amino acids long on average or 3.2×10^6 possible antibodies." Plaintiffs' Brief, at 15. Because "many of the encoded peptides will present sufficiently similar binding surfaces that a single antibody will react with any of them. In other words, it is not necessary to have all, or even most, of the possible coding sequences represented." Id., at 15 (quoting from File History, at 202). In fact, "all possible antibodies will be found to bind specifically with one of the mixture of random peptides provided a) the peptides are 5-7 amino acid residues in length, and b) the mixture contains at least about 10% of all possible peptide sequences." Id. (quoting File History, at 200). Therefore a library of "about" 300,000 members is all that is required to identify the "universe" of possible antibody binding sites. Id.

This assertion is the crux of the dispute about the necessary size of the specified library because, as a matter of undisputed scientific fact, there are 20 naturally occurring amino acids. Thus, where the peptide length consists of 5 amino acid residues, the possible

number of peptides is 20^5, or more conventionally stated, 3.2×10^6. Where, however, the length is 12 amino acid residues, the possible number of peptides is 20^{12} or 4.096×10^{15}. It follows that a library containing 10% of all *possible* peptide sequences where the length is 12 would contain 4.096×10^{14} members, as Dr. Pieczenik himself pointed out to the PTO in correcting the examiner's assumption that the correct formula for calculating the possible number of peptide sequences where L is 12 is the inverse of 20^{12},

or 12^{20}. In traversing the examiner's rejection, Dr. Pieczenik gave the following example. "For a peptide having a sequence length of 12 (L = 12), each position having an equal probability of being one of the 20 natural amino acids (N = 20), the number of possible sequences is $N^L = 20^{12}$, which can be converted to 4.1×10^{15}." Dyax Brief, at 21 (quoting File History, at 734). He went on to point out that the examiner's method resulted in a million-fold error on the high side. Id. (quoting File History, at 735).[6] The point is crucial because, as Dyax points out, "the peptides in [its] libraries are longer than 12 amino acids -- indeed, some are longer than 60 amino acids. And, Dyax's phage display libraries include far fewer than 10% of the possible peptide sequences for a selected peptide length." Dyax Brief, at 9. A library of 300,000 members would represent but 0.0000000073% of the *possible* number of sequences where L is 12, when the formula advocated by Dyax and used by Dr. Pieczenik

in his illustration to the PTO is applied. See Table, Dyax Reply, at 5. None of the corresponding percentages for lengths 6 to 13, which range from 0.47% (6) to 0.00000000037% (13), could ever reasonably thought to be "about 10%," no matter how flexibly the limitation is to be read. It is therefore critical to an understanding of plaintiffs' position to trace the elements of the argument that the "said" in the phrase "all possible peptide sequences of said length," refers to pentapeptides.

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[6] Plaintiffs maintain that Dr. Pieczenik was taken out of context and was referring to the correct method of calculating the number of theoretically possible sequences and not the number of sequences that are biochemically possible. Plaintiffs' Response, at 13-14. This distinction, however, appears nowhere in the exchange with the examiner.

To the extent that plaintiffs' argument is based on the actual language of claims 24 and 34, it rests on the supposed difference between the meaning of "selected length" (the term used in the antecedent application) and the term "said length" (the term ultimately chosen). "Whereas *selected* refers to the random

length selected *a priori, said* refers to the length of the random peptide sequence that, for example, ***binds*** to an antibody."[1] Plaintiffs' Response, at 8 (emphasis in original). This semantic change, plaintiffs argue, would have alerted an attentive reader of ordinary skill in the art, familiar with the "scientific presumption" that "antibodies are now known to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids," to the fact that a pentapeptide library is sufficient to define all peptide sequences with lengths from 6 to 13 amino acid residues. Id., at 10. In other words, a library of 300,000 distinct figures (roughly 10% of 3.2×10^6) would completely satisfy the 10% limitation in the claims. "Said" is a term used by patent drafters who (like many lawyers) are unexplainably uncomfortable with using the more colloquial "the" when referring back to previously recited claim elements. See Landis on Mechanics of Patent Claim Drafting (2001) § 23. Neither claim 24 nor claim 34 makes any antecedent reference to pentapeptides as the sequence defining the "said" length. The element referenced is rather "a length from about 4 to about 12 nucleotide triplets," that is, one of 9 (or 10)

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[1] As Dyax points out, this assertion contradicts the specification of the patent, which teaches that "the invention features a discrete recombinant vector population of substantially identical

autonomously replicating nucleic acid sequences including a structural gene and a population of oligonucleotide inserts therein, each insert containing a uniform length *selected* from between about 4 to about 12 nucleic acid coding triplets, preferably between 4 and 7, and most preferably five. `393 patent, Col. 4, Ins. 19-27 (emphasis added). designated lengths with its corresponding peptide sequence. Pentapeptides are certainly one of these lengths, but not the only length referenced. The claims language, in other words, simply will not support the load bearing weight plaintiffs attempt to assign to the word "said."

Plaintiffs' prosecution file history and prior art arguments fare no better. Much emphasis is placed on the qualified disclosure in the original 1985 application that the size of the antibody recognition site corresponds to a peptide sequence in the range of between about 4 and about 12 amino acid residues . . . [and that] there are about three million (20^5) different possible sequences of the twenty amino acid residues taken five at a time and about sixty million if the amino acid residues are taken six at a time. This finite number of peptide sequences may represent the full range of possible antibody recognition sites. Production and maintenance of a representative sample of the peptide sequences of

the appropriate length provides the means (1) to screen any antibody of interest in order to determine the precise peptide sequence it binds to ....

Plaintiffs' Brief, at 12 (quoting File History, at 14-15).[8] From this, plaintiffs deduce that it would have been "clear" to one skilled in the art that the inventor had "recognized that random pentapeptides can adequately represent any random 12 amino acid sequence in terms of competitive binding to antibodies." Id., at 12-13. Why this is so is not explained in any meaningful way, other than by random citations to the discussion of the prior art in the original 1985 patent application, which when read in context, offer no support for

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[8]As Dyax argues, the assertion that the range of 3 to 60 million peptides represents the universe of possible antibody recognition sites ignores antibodies that bind conformationally dependent epitopes "for which pentapeptides and hexapeptides cannot successfully compete in many circumstances." Dyax Brief, at 25 n*. According to Dyax, when these are considered the number of possible antibody recognition sites "far exceeds" the 3 to million figure posited by Dr. Pieczenik. Even if the 3 to 60 million figure is correct, plaintiffs do not explain why the absolute bottom of that range represents the operative number of desired peptides.

plaintiffs' late blooming theory that the `363 patent teaches a universe of antibody binding sites bounded by pentapeptides. The citation to Geyson, *et al.,* in the file history is a good example. It is clear in context that Geyson was cited to explain to the PTO why degeneracy (the phenomenon by which an antibody may recognize more than one peptide sequence) made it possible to construct a working population consisting of only 10% of the peptides of a given length rather than, as the examiner thought would be necessary, the entire peptide population associated with that length. It does not follow from the discussion of Geyson (or Dame, et al., the other principal prior art source cited) that the "prosecution file history make[s] clear to one skilled in the art that any coded library of random peptides with [a] length in the range of 5-13 amino acid residues and containing at least about 300,000 (e.g. 30,000 = 1%) distinct members is understood to mean an oligonucleotides population that *represents at least about 10% of all possible peptide sequences of said length."* Plaintiffs' Brief, at 15-16 (emphasis in original).

Conclusion

The limitation establishing a library of peptide sequences representing "at least about 10% of all possible peptide sequences" of "from about 4 to about 12 L-amino acid residues" has one definite term -- "all possible" -- and two indefinite terms -- "at least about 10%" and "from about 4 to aboutl 2." There is no indication in the

patent specification that Dr. Pieczenik intended these phrases to convey any meaning other than their ordinary English connotation. Thus, "all possible" can only be understood to mean the universe of peptide sequences associated with L-amino acid lengths of "from about 4 to about 12." While I agree with plaintiffs that the term "about" is a term of deliberate imprecision that might fairly capture the integers 3 and 13 at the boundaries of "from about 4 to about 12," the term "all possible" can only mean in context the entire universe of what could occur, that is, the total number of naturally occurring sequences that can possibly be associated with the selected length, whether 20^3 or 20^{13} or some other specified length within the asserted range of 3 to 13 amino acid residues. In similar fashion, in the interest of lexicographic consistency, "at least about 10%" can be understood to perhaps capture 9%, or given the qualification of "at least about 10%," perhaps a number substantially above 10%, but certainly not 1°/o, as plaintiffs' expert, Dr. Makowski, maintains.[9]

As Dyax points out, plaintiffs' redefinition of the universe of antibody binding diversity as corresponding with a population of pentapeptide sequences "reads out" of the claims the range of peptides of from 6 to 12 amino acids in length "by making them synonymous with the 5 amino acid member of the range." Dyax

Brief, at 27. Like Dyax, I am puzzled why, if the point of the invention was to provide a population of peptide sequences representing the "universe of possible antibody binding sites," the claims would have been written "to specify lengths of peptides that admittedly cannot do so," or why it is not simply made clear that pentapeptide sequences define the intended universe. Dyax Response, at 8. Indeed, there is nothing said at all in the claims (or the specification) about this universe, nor is any meaningful suggestion made that longer peptides can be expressed as representative lengths of pentapeptides. Like Dyax, I can only conclude that

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[9] That the phrase "at least about 10%" means "more than at least 1%" was the position taken by Dr. Makowski in his deposition. It is not clear from the briefs whether plaintiffs continue to support Dr. Makowski on this point, or whether even Dr. Makowski believes that the 1% figure is supported by the patent. See Dyax Brief, at 29; Plaintiffs' Response, at 14.

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plaintiffs' "pentapeptide universe" theory is an attempt to expand

on the claims of the patent to broaden their coverage for purposes of this litigation.[10]

Oligonucleotide

With respect to the '535 and '266 patents, plaintiffs indicate agreement with the construction advanced by Dyax with the exception of the meaning of the limitation "oligonucleotide." Plaintiffs' Response, at 12-13. Plaintiffs maintain that "oligonucleotide" as used in these two patents would be understood by a person of ordinary skill in the art "to mean a polymor [sic] of nucleotides comprising at least a few nucleotides in length and not usually more than about 100," although they insist that the term is given a "broader" meaning in the `363 patent. Plaintiffs' Brief, at 18, 19. According to plaintiffs, the file history of the '363 patent "makes clear" that the term "oligonucleotide" as used in that patent signifies an oligonucleotide with "an upper limit at about 600 to about 750 nucleotides triplets in length." Id., at 8. This assertion is apparently based on a reference by Dr. Pieczenik in the prosecution file history to an oligonucleotide containing 50 tandem sequences of from about 4 to about 12 nucleic acid triplets (hence 50 x 12 = 600). Id.[11]

I find no support in the patent for plaintiffs' narrow or broad definition of oligonucleotide. An oligonucleotide is defined in scientific and medical texts as a

[10]While it is true that the `393 patent identifies populations of 5 amino acid length sequences as a preferred embodiment of the invention, it is only one of four such preferred embodiments (the others being populations of sequences 4, 6, and 7 amino acids long). Moreover, as plaintiffs acknowledge, "[r]eferences to a preferred embodiment, such as those often present in a specification, are not claim limitations." Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988).

[11]The source of the 750 figure is not revealed.

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compound created by the condensation of a small number of nucleotides with 20 specified as the upper limit. See, e.g., Stedman's Medical Dictionary (26th ed. 1995) 1244. As for the idea that the upper limit might be as high as 600 or 750 triplets based on Dr. Pieczenik's stray remark, neither claim 24 nor claim 34 makes any reference to an oligonucleotide made up of tandem sequences. See Markman, 52 F.3d at 980 ("Although the prosecution history can and should be used to understand the language used in the claims, it too cannot `enlarge, diminish, or vary the limitations in the claims").

ORDER

For the foregoing reasons, the court for Markman purposes will construe the disputed terms as follows. The limitation "from about 4 to about 12 nucleotide triplets," as used in claims 24 and 34 of the '363 patent, is sufficiently indefinite to include a range whose boundaries are delimited by 3 and 13. Similarly, the limitation "from about 4 to about 12 L-amino acid residues" means a range of from 3 to 13 of such residues. The limitation "represents at least about 10% of all possible peptide sequences" means approximately 10% or more of the possible peptide sequences of a given length within the range of 3 to 13 L-amino acids where the number of possible peptide sequences is equal to 20^{l}. "Oligonucleotide" means a compound created by the condensation of typically fewer than 20 nucleotides.

SO ORDERED.

Richard D. Stearns

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WHEREAS on August 12, 2003, the United States Patent and Trademark Office issued Patent No. 6,605,448 B1 ("the '448 patent") to the Plaintiff, Dr. George Pieczenik, *pro se*; and

WHEREAS on February 2, 1999, the United States Patent and Trademark Office
Issued Patnet No. 5,866,363 ("the '363 patent") to the Plaintiff, Dr. George Pieczenik, pro se; and

WHEREAS on October 16, Dr. Richard Roberts, Research Director of New England Biolabs, was served with a subpoena for sales information from New England Biolabs from 1997 to the present; and

WHEREAS, the information requested in the subpoena is confidential business information of New England Biolabs; and

WHEREAS, no part of the restrictions imposed by this Protective Order may be terminated or amended, except by the written stipulation of counsel of record and counsel for New England Biolabs, **or by an order of this court for good cause shown**, provided that counsel

for New England Biolabs has had an opportunity to be heard on any motion to amend this Protective Order; and

WHEREAS, the information requested shows that Robert Ladner in his Affidavit as Vice President and Chief Scientific Officer for Dyax and their lawyer's at Fish & Neave, particularly, Chris Harnett, shows that they both in serial and individually gave fraudulent information on **denying having** the New England Biolabs (NEB)phage display combinatorial libraries which infringe the Pieczenik patents **after Feb. 2, 1999**, in Appendix A –p A3541 para 8 "For example, Exhibit A to the present affidavit identifies additional Dyax libraries that were made, used or sold before February 2, 1999." In Appendix A p. A3555 shows NEB libraries C7C, NEB library PhD-7, NEB library PhD-12; and

WHEREAS, the New England Biolab sales record shows sales (Appendix B) to Dyax of the Ph-7 phage Display Peptide Product No. 8100 and Ph-12 phage Display Peptide Product No.8110 shipped on August 9th , 1999, 8/09/1999, which means it was **shipped SIX MONTHS AFTER Feb 2, 1999 to Dyax from NEB**; and

WHEREAS, this is direct evidence for infringement, and the crux of the infringement case, as the New England Biolab Ph.7 combinatorial library falls completely within all the elements of the most rigid and literal construction of the

claims in the '363 and the '448 patent by the Markman ruling of the Boston Court and the Court of Appeals in the Federal Circuits recent ruling; and

WHEREAS, this is *res ipsa loquitur* evidence for fraud, by Dyax and its lawyers, on the District Court, the Court of Appeals for the Federal Circuit and now even the Supreme Court which may consider a Writ of Certiori on this and other issues, and

I , NOW,

Therefore, request that this Court allow the Protective Order of Confidentiality of this New England Biolabs Sales Information be extended to include the Boston District Court, the Court of Appeals for the Federal Circuit and the Supreme Court; and

That Fish & Neave lawyers address the issue of this fraudulent affidavit and their knowledge, thereof,

Respectfully Submitted,

November 24, 2003

D. George Pieczenik

Order Affirmed by Judge Shira Scheindlin, SDNY on 12/15/03